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10/804,825	03/19/2004	Paul C. Davidson	820802-1010	7112
24504 7590 03/06/2007 THOMAS, KAYDEN, HORSTEMEYER & RISLEY, LLP 100 GALLERIA PARKWAY, NW STE 1750 ATLANTA, GA 30339-5948			EXAMINER WHALEY, PABLO S	
			ART UNIT	PAPER NUMBER
			1631	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/804,825	<b>Applicant(s)</b> DAVIDSON ET AL.	
	<b>Examiner</b> Pablo Whaley	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12/21/2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 132-268 is/are pending in the application.
- 4a) Of the above claim(s) 135, 139, 146, 148, 153, 168, 169, 170-172, 178-179, 183, and 196-197 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 132-134, 136-138, 140-145, 147, 149-152, 154-167, 173-177, 180-182, 184-195 and 198-268 is/are rejected.
- 7) ☒ Claim(s) 208 and 209 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION***APPLICANT'S ELECTION*

Applicants' election, filed 12/21/2006, of Specie A (claim 134), Specie B (claim 140), Specie C (claim 147), Specie D (claim 151), Specie E (claim 154), Specie F (claim 167), Specie G (claim 184), Specie H (claim 193). Applicant's traversal of claim Specie D is acknowledged and is persuasive, as claim 152 depends from claim 151. The specie election drawn to Specie D is hereby withdrawn. Claims 135, 139, 146, 148, 153, 168, 169, 170-172, 178-179, 183, and 196-197 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/21/2006. Claims 1-131 are cancelled.

*CLAIMS UNDER EXAMINATION*

An action on the merits of claims 132, 133, 134, 136-138, 140-145, 147, 149-152, 154-167, 173-177, 180-182, 184-195, and 198-268 follows, as they read upon the elected species.

*DRAWINGS*

Drawings filed 3/19/2004 have been accepted.

*PRIORITY*

Priority to US Provisional Applications 60/456,271, filed 3/19/2003 and 60/532,487, filed 12/26/2003, and 60/543,576, filed 2/11/2004 has been acknowledged.

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*OBJECTIONS*

Claim 204 is grammatically incorrect. Claim 204 should recite "the feedback factor is the quantity: (the current ratio of Basal Insulin to total daily dose of insulin)." Correction is required.

Claim 208, which currently depends from claims 200 and 202, is in improper form because a multiple dependent claim should refer to other claims in the alternative only, and cannot depend from any other multiple dependent claims. Claim 209 is also object to as it depends from claim 208.

**CLAIM REJECTIONS - 35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 132, 133, 134, 136-138, 140-145, 147, 149-152, 154-167, 173-177, 180-182, 184-195, and 198-268 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. A statutory process must include a step of a physical transformation of matter, or produce a concrete, tangible, and useful result [State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998)], [AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999))].

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The instant claims are generally directed to a method for adjusting an insulin dosing schedule involving a time interval of a patient's day. It is noted that while claim 132 recites "dosage administered", this is not an active method step. Thus, the instant claims comprise steps that do not result in a physical transformation of matter, as the claimed method steps are not limited to physical steps (i.e. steps done by a user), and therefore encompass non-physical method steps that may be practiced inside of a computer (i.e. *in-silico*). Where a claimed method does not result in a physical transformation of matter, it may be statutory where it recites a result that is concrete (i.e. reproducible), tangible (i.e. communicated to a user), and useful result (i.e. a specific and substantial). In the instant case, the claims ultimately result in new insulin dosing parameters, but lack a tangible result as nothing is communicated to a user such that it is useful to one skilled in the art. For these reasons, the instant claims are not statutory.

This rejection could be overcome by amending the claims to recite that a result of the method is "displayed" or "outputted" (e.g. output to a user, a display, a memory, or another computer, etc.), or by amending the claims to include a step of a physical transformation of matter (e.g. assay). For an updated discussion of statutory considerations with regard to non-functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter in the MPEP 2106, Section IV.

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**CLAIM REJECTIONS - 35 USC § 112, 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 132, 133, 134, 136-138, 140-145, 147, 149-152, 154-167, 173-177, 180-182, 184-195, and 198-268 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 132 is directed to a method of adjusting an insulin dosing schedule "involving a time interval of a patient's day." As the instant claims do not recite any active methods steps directed to "adjusting" an insulin dosage schedule, or "administering" dosages to a patient, it is unclear in what way the claims achieve the purpose of the preamble. Clarification is requested. The Examiner has broadly interpreted this claim for purposes of applying prior art.

Claims 132, 144, 150, 154, 156, 157, 161, 163, 164, 173, 174, 176, 192-195, 201, 202, 204, 205, 206, 207, 209, 216, 234, 236, 242, 243, 244, 245-247, 263, and 266-268 recite the use of parentheses. It is unclear whether the limitations inside of the parentheses are intended to be different types of parameters, positive limitations of the method, variables, or something else. If applicant intends the limitations inside the parentheses represent different parameters, applicant is encouraged to amend the claims such that they clearly delineate each type of dosing parameter. Clarification is requested via clearer claim language.

Claim 132 recites the limitation "further involving the use of data...to determine new insulin dosing parameters." It is unclear in what way "the use of data" are further

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involved in the claimed method. Therefore the metes and bounds of "involving" cannot be understood. Clarification is requested.

Claim 132 recites "an old Basal Insulin an old Meal Insulin, and an old Corrective Insulin." It is unclear whether these limitations are intended to be values, dosages, or something else. Correction is requested.

Claims 132 and 175 recite "a new Carbohydrate-to-Insulin Ratio." There is lack of antecedent basis for this limitation. It is noted that the instant claim does not previously recite any limitation directed to a Carbohydrate-to-Insulin ratio. Correction is requested.

Claim 133 recites the limitation "the use of blood glucose test results as an indicator." There is lack of antecedent basis for this limitation. Furthermore, it is unclear in what way said test "results as an indicator." Correction is requested.

Claim 141 recites the limitation "the changes are introduced." There is lack of antecedent basis for this limitation. Correction is requested.

Claims 142, 154, and 210 recite "stem changes." As the specification has not provided a limiting definition for the term "stem changes", the metes and bounds of "stem changes" cannot be understood. Clarification is requested.

Claim 144 recites the limitation "Carbohydrate-to-Insulin Ratio." There is lack of antecedent basis for this limitation. It is noted that parent claim 132 recites a "new" Carbohydrate-to-Insulin Ratio. Correction is requested.

Claim 147 recites the limitation "the invention program." There is lack of antecedent basis for this limitation. Correction is requested.

Claim 158 recites the limitation "the change for Basal Rate." There is lack of antecedent basis for this limitation. It is noted that parent claim 132 recites "Basal Insulin." Correction is requested.

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Claim 175 recites the limitation "the new value." There is lack of antecedent basis for this limitation. Furthermore, it is unclear as to exactly what "new value" applicant is referring. Correction is requested.

Claim 193 recites "the multiplying factor (Krxlnsl)" and later "(Krxlnsl is a stem parameter)." It is unclear whether applicant intends for "Krxlnsl" to be a "multiplying factor" and a "stem parameter. Clarification is requested.

Claim 205 recites "an access protocol that is not normally known by the patient." It is unclear in what why this further limits the claimed method, as the metes and bounds of "protocol that is not normally known" cannot be determined. Clarification is requested.

Claim 213 recites the limitation "the does not require the amount of carbohydrates by multiplying a change for Meal Insulin by the calculus derivative of carbohydrate-to-insulin ratio with respect to Meal Insulin." There is lack of antecedent basis for "the calculus derivative of carbohydrate-to-insulin ratio with respect to Meal Insulin." Furthermore, it is unclear in what way this limitation further limits the claimed method, as the instant claims do not recite any active method step directed to calculating a derivative. If applicant intends for this limitation to be an active method step, the claim should be amended to reflect this intention using active language. Clarification is requested.

Claims 237 recites "wherein the change to Prescription Insulin is adjusted based on a percent standard deviation..., and wherein if the patient's standard deviation is higher..., then less change...is employed than the change determined". It is unclear in what way change is "based on" a percent standard deviation. It is also unclear in what way "then less change...is employed than the change determined" further limits the claimed method, as this limitation is unintelligible. Clarification is requested.

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Claims 258 and 259 recite the terms "but seldom performed" and "but seldom does so." The term "seldom" is a relative term of degree. Therefore it is unclear as to the metes and bounds of the term "seldom" in the given contexts. Furthermore, it is unclear in what way these limitation further limit the claimed method. Clarification is requested.

### **CLAIM REJECTIONS - 35 USC § 102**

The instant claims appear to be directed to a method of adjusting an insulin dosage schedule involving a base insulin dosage over a given time interval (Basal Insulin) coupled with an additional insulin dosage administered in relation to a meal taken during a given time interval (Meal Insulin) for determining new dosage parameters. It is noted that for purposes of prior art, the Examiner has examined the instant claims using the broadest, reasonable interpretation.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 132, 133, 134, 136-138, 140-145, 147, 149-152, 154-157, 158-161, 162, 163, 164, 165, 166, 167, 175, 189-191, 198, 199, 211, 212, 224, 225, 226, 250-253, and 258 are rejected under 35 U.S.C. 102 (b) as being anticipated by Kaufman et al. (Diabetes Metab. Res. Rev., 1999, Vol. 15, p.338-352).

The instant claims appear to be directed to a method of adjusting an insulin dosage schedule involving a base insulin dosage over a given time interval (Basal Insulin) coupled with an additional insulin dosage administered in relation to a meal taken during a given time interval (Meal Insulin).

Kaufman et al. teach a method for adjusting an insulin dosing schedule for an insulin pump based on basal rates, carbohydrate bolus doses, correction bolus based on meals, and corrective insulin dosages based on blood sugar testing and time intervals (daily and hourly) [Table 4], [Table 5], and [p.343, Col. 2, ¶ 2], as in claims 132, 133, 134, 136-138, 140-145, 147, 149-152, 154-157, 158-161, 162, 163, 164, 165, 166, 167, 175, 189-191, 198, 199, 211, 212, 224, 225, 226, 250-253, and 258. More specifically, Kaufman et al. also teach the following aspects of the instant claims:

- Guidelines and formulas for determination of new insulin values based on meals (i.e. carbohydrates) and correction of blood glucose levels outside a target range [p.344, Col. 2, ¶ 2] and corrective insulin dosages based on blood glucose testing algorithms for adjusting basal and bolus insulin regimens based on changes in blood glucose levels [p.344, Col. 1, Table 7], as in claims 141, 142, 151, 152, 198, 199.
- Calculating the subcutaneous insulin dosage history, calculating an amount of insulin per carbohydrate (i.e. carbohydrate to insulin ratios), at dawn (i.e. rising from sleep), elevated blood glucose level, basal and bolus ratios [Table 6] and at different time intervals [Table 5] and [Fig. 4], as in claims 132, 140, 143, 144, 145, 149, 150, 151, 152, 154-157, 162, 163, 164, 165, 166, 167, 175, 189, 190, 191, 211, 250, 251, 252, 253.
- Insulin pump devices with downloadable cradle that do not provide for memory of

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carbohydrate amounts [Fig. 3], as in claims 147 and 212.

- Corrective insulin dose changes based on input of pre-meal times, basal dosages, and blood sugar levels, and subtraction of values [Fig. 4], as in claims 158-161, 189-191, 224, 253, 258.
- Insulin dosage scheduling based on exercise [Table 5], as in claim 225, 226.

Claims 132, 133, 134, 136-138, 140-144, 150, 159, 160, 161, 164, 165, 166, 173-177, 180-182, 184-188, 192-195, 200-223, 227-229 are rejected under 35 U.S.C. 102 (e) as being anticipated by Galley et al. (US 2003/0028089, Filed Jul. 31, 2001).

Galley et al. teach a diabetes management system comprising an insulin delivery unit, a control unit, and a glucose sensor, for determining corrective insulin dosages when predictive glucose values lie outside of pre-determined ranges for calculating precise amounts of insulin required to keep a user's blood sugar concentration at a previously set target [Abstract]. More specifically, Galley et al. teach additional intervention boluses (i.e. additional dosage) and delivered insulin in response to blood glucose values (i.e. corrective doses) [Fig. 5] and [0026]. Galley et al. also provide means for blood glucose testing and blood sample collection [0028]. Galley et al. also teach feed-back and feed-forward algorithms and equations for calculating insulin dosages based on carbohydrate-to-insulin ratios, scaling factors, total insulin dosage, carbohydrates, insulin-to-carbohydrate ratio, and linear fit intercept values (i.e. statistical correlation values) [Fig. 7], [0009], and [0063-0069]. Galley et al. also teach infusion rate constraints based on fractional values ( $\beta$ ) and basal rates [0070-0072]. Galley et al. also teach a feedback algorithm expressed as a function of basal insulin, normalized insulin values (i.e. ratios), meal-related insulin doses, recommended insulin doses,

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target blood glucose values, sensitivity factors, time intervals between insulin cycles [0034] and [0040-0055], and related summation equations [p. 4, Col. 2, Equations 1, 2, and 3]. Galley et al. also teach user-input carbohydrate amounts, meal types, and glycemic indexes [0069], and infusion rates (i.e. derivate) [0070].

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 132, 133, 134, 136-138, 140-145, 147, 149-152, 159, 160, 161, 164, 165, 166, 173-177, 180-182, 184-188, 192-195, 200-223, 227-249, 254-268 are rejected under 35 U.S.C. 103(a) as being made obvious by Albisser et al. (Medical & Biological Engineering & Computing, 1986, Vol. 24, p.577-584), in view of Ribeiro (US 2003/0055570, Filed Aug. 28, 2001).

Albisser et al. teach a method for adjusting insulin dosages comprising new insulin dosage values derived from iterative basal insulin dosages (both before and after

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meals), wherein dosages are administered over days and are adjusted using blood glucose test results coupled with additional multiplying factors [p.578, Col. 1, ¶ 4 and Col. 2]. More specifically, Albisser et al. also teach the following aspects of the instant claims:

- Insulin injected dosages fixed (i.e. basal insulin) and then adjusted over time in response to meals (i.e. meal insulin) [Fig. 3] and [p.581, Section 3.1.3], wherein adjusted (i.e. corrective) insulin dosages (IAID, IAIB, SAIB, SAID) are calculated based on patient blood glucose information, carbohydrates, and effects are measured according to blood glucose tests [p.578, Col. 1, ¶ 4 and Col. 2], as in claim 132, 133, 164, 165, 167, 187-188. As this is an iterative algorithm, the above process is an inherent teaching for the calculation of "new" mean insulin values, as in claims 154-159 and 173-177.
- Iterative feedback algorithm and equations for adjustment of insulin dosage values based on the addition/subtraction of quotient comprising the  $\Sigma$  of glucose values, sensitivity factors (i.e. correction factors), plasma levels based on food intake, insulin dosages values from the previous day (i.e. old values), successive dosing cycles, ratios, and days [p.578, Equations 1-4], as in claims 180-182, 184, 185, 192-195, 198, 199, 200, 201, 210.
- Treatment scenarios for patients based on expert practitioner prescribed dosages and computer simulated dosages before and given time intervals, and statistical comparison (i.e. change) [Table 1, Table 2, and Fig. 3], as in claims 160, 161, 186, 219
- Daily dosage adjustment using the insulin dosage computer algorithm [Section 3.1.3, p. 581]

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- User information comprising glucose levels with upper and lower boundaries based on future carbohydrate amounts ingested after meals [Table I and II].

Albisser et al. do not specifically teach limitations directed to “carbohydrate-to-insulin ratios” and “blood concentration targets” as in claims 144 and 230. However, Albisser et al. do teach methods for measuring blood glucose levels during meals and related insulin rates, as set forth above, which makes obvious the use of carbohydrate-to-insulin ratios, as required by the instant claims. Albisser et al. also do not specifically teach the limitations of claims 230-240, 245-247, 262-269, directed to specific equations and formulas for practicing the claimed method.

Ribeiro teaches a method and computer system for calculating precise amounts of insulin required to keep a user's blood sugar concentration at a previously set target [Abstract] and [0100] and [Fig. 1 and 2]. Ribeiro also teaches the following aspects of the instant claims: a method and device for determining subject's blood sugar level, amount of carbohydrates, amount of insulin forecasted in a single day, and calculating appropriate amount of insulin based on sugar level, carbohydrates, and forecast amount of insulin [Ref. Claim 132]; insulin-carbohydrate ratios (i.e. old and new), pre-meal and post-meal blood sugar levels (i.e. target and measured), and insulin sensitivity [Ref. Claim 4]. It is noted that Ribeiro does not specifically teach all of the specific limitations as recited in claims 230-240, 245-247, and 262-269. However, Ribeiro makes obvious the plurality of user-entered variables and equations for calculating total daily insulin amounts, blood sugar readings set by the physician and user as targets, quantity of carbs, bolus values, insulin ratios, carbohydrate ratios, standard deviation values from target, insulin per day values [Figs. 4, 5, 6, and 9] and [0035-0071]. As the instant claims do not recite clearly delineate specific equations and related parameters required for

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practicing the claimed method, the limitations as recited in 230-240, 245-247, 262-269 have not been given patentable weight over the teachings of Ribeiro.

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the insulin dosage adjustment algorithm taught by Albisser et al, by incorporating the additional parameters and equations for insulin bolus calculation beneficially taught and provided by Ribeiro, where the motivation would have been to improve conventional insulin therapy and short-acting insulin dosages [Ribeiro, Section 0118] with respect to the art-recognized method of estimating a patient's insulin sensitivity and insulin dosage based upon factors such as pre-meal and post-meal blood sugar levels, carbohydrate content, and timing of dosage, as provided by Ribeiro, resulting in the practice of the instant claimed invention. One of skill in the art would have had a reasonable expectation of successfully combining the method of Albisser et al. with the calculation program of Ribeiro as both teach methods for insulin dosage and blood glucose monitoring.

Claims 132, 133, 134, 136-138, 140-145, 147, 149-152, 154-157, 158-167, 173-177, 180-182, 189-195 198, 199, 200-229, 250-253, and 258 are rejected under 35 U.S.C. 103(a) as being made obvious by Doyle et al. (Proceedings of the 23<sup>rd</sup> Annual EMBS International Conference, Istanbul, Turkey, Oct. 2001, p.1-4), in view of Galley et al. (US 2003/0028089, Filed Jul. 31, 2001).

Doyle et al teach a control method for adjusting the insulin dosage schedule of an individual, wherein the dosage and timing of insulin is estimated based upon patient history and desirable glucose levels. Furthermore, Doyle et al teach a method wherein the glucose response to at least one meal is observed and then used in conjunction with

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the patient's insulin sensitivity and initial dose of insulin to estimate the pre-prandial dosage and timing of insulin for the following day's meal (i.e. meal insulin), which may be equal to, or different from, the initial insulin dose. Doyle et al. teach equations that correlate timing and quantity of insulin injection, maximum/minimum glucose values  $G_{max}$  and  $G_{min}$  (i.e. feedback correction values) that vary between positive and negative [p.2, Col. 1, Section B]. Doyle et al also teach that the corrections in insulin dosage are based upon the post-prandial (i.e. after meal) glucose measurements from the previous day and also take into account caloric differences among the meals and timing of insulin [Section IIB and IIC]. Doyle et al further teach a method wherein the maximum glucose levels following each meal are maintained in the normal glycemic range, and progressively improve (i.e., optimize over time) and converge to provide an insulin profile (i.e., a predetermined target range) [Section IIIB]. In addition to the above-described method, Doyle et al also teach a method wherein the above steps are repeated during a 24-hour period, during which meals are ingested at variable times during the period, wherein meals are ingested more than 3 times during the day or fewer than three times during the day. Furthermore, Doyle et al teach that this method can be used either in a continuous fashion for constant fine-tuning, or on a periodic basis to allow re-calibration wherein the amount and timing of insulin delivery is updated (i.e., feedback control) [Section IIIA].

Doyle et al do not specifically teach a method wherein insulin dosage corrections incorporate the carbohydrate content of a meal, or measurements obtained from a blood glucose test. Doyle et al. also do not specifically teach the limitations and variables as recited in claims 142, 144, 150, 154, 161-167, 173, 176, 193, 202-207, 213-218, and 220-229.

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Galley et al. teach a diabetes management system comprising an insulin delivery unit, a control unit, and a glucose sensor, for determining corrective insulin dosages when predictive glucose values lie outside of pre-determined ranges for calculating precise amounts of insulin required to keep a user's blood sugar concentration at a previously set target [Abstract]. More specifically, Galley et al. teach additional intervention boluses (i.e. additional dosage) and delivered insulin in response to blood glucose values (i.e. corrective doses) [Fig. 5] and [0026]. Galley et al. also provide means for blood glucose testing and blood sample collection [0028]. Galley et al. also teach feed-back and feed-forward algorithms and equations for calculating insulin dosages based on carbohydrate-to-insulin ratios, scaling factors, total insulin dosage, carbohydrates, insulin-to-carbohydrate ratio, and linear fit intercept values (i.e. statistical correlation values) [Fig. 7], [0009], and [0063-0069]. Galley et al. also teach infusion rate constraints based on fractional values ( $\beta$ ) and basal rates [0070-0072]. Galley et al. also teach a feedback algorithm expressed as a function of basal insulin, normalized insulin values (i.e. ratios), meal-related insulin doses, recommended insulin doses, target blood glucose values, sensitivity factors, time intervals between insulin cycles [0034] and [0040-0055], and related summation equations [p. 4, Col. 2, Equations 1, 2, and 3]. Galley et al. also teach user-input carbohydrate amounts, meal types, and glycemic indexes [0069], and fractional infusion rates (i.e. derivate) [0070-0071]. As the instant claims do not recite clearly delineate specific equations and related parameters required for practicing the claimed method, the limitations as recited in 142, 144, 150, 154, 161-167, 173, 176, 193, 202-207, 213-218, and 220-229 have not been given patentable weight over the teachings of Galley et al.

Thus it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the control method disclosed by Doyle et al. by

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incorporating additional parameters beneficially taught and provided by Galley et al., as meal size and duration cause variation in blood glucose levels and thus are important factors in determining the appropriate amount and timing of pre-meal and post-meal insulin dosing, as taught by Galley et al. [0021]. One would have been motivated to incorporate the teachings of Galley et al. into the glucose control method taught by Doyle et al. so as to derive the optimal dosage of insulin to provide both the basal insulin requirement and the meal-related insulin dosing of an individual for the expected benefit of improving patient control over blood glucose levels and preventing postprandial hyperglycemia, a risk factor for coronary heart disease in diabetic patients. One of skill in the art would have had a reasonable expectation of successfully combining the method of Doyle et al. with the parameters of Galley et al. as both teach methods for insulin dosage and blood glucose monitoring.

### CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached at 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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